Summary of the
Quality Systems Committee Meeting
February 4, 1997

The National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems Committee met from 9 a.m. to 5 p.m. Eastern Standard Time (EST) on February 4, 1997. The meeting was led by Ms. Silky Labie, chair, Florida Department of Environmental Protection. A list of action items is given in Attachment A. A list of Committee members present is given in Attachment B.

INTRODUCTION

The purpose of the meeting was to continue to review revisions to Chapter 5, "Quality Systems." The following items were discussed according to the prepared agenda:

- Performance audits,
- Laboratory reports,
- Subcontracting analytical samples,
- Checklist for demonstration of method performance,
- Initial demonstrations of capability,
- Checklist format,
- Spiking compounds,
- Radioanalysis, and
- Revisions to current standards.

DISCUSSION OF PROPOSED STANDARDS

5.5.3.4 -- Performance Audits

This section was rewritten in July. No additional comments were made by the participants.

5.13 -- Laboratory Report Format and Content

The value of providing the report to the facility's management was questioned, noting that it includes too much detail. All the data are on file in the laboratory, so providing it to management would simply result in meaningless duplication. Management does not typically sign off on the report and so it does not need the data. The Committee agreed that a definition of who is the manager of the data is needed.

5.13.a.10
It was noted that this provision might result in a lot of paperwork as many laboratories do not follow their standard operating procedures (SOPs). The Committee indicated that this provision might force the laboratories to follow the SOPs more closely.

5.13.a.11
Participants asked if it is necessary to include the methods and quality control (QC) information in the report. The data are retained by the laboratory and can be sent to the client if requested. Any failures or deviations from the QC, however, should be noted, as should anything affecting the quality or accuracy of the data.

5.13.a.12
Trace analysis may be unrealistic. One suggestion was to change it to "background level" and to remove "where there is an uncertainty associated with detection limits."

5.13.a.13(d)
The laboratory should provide the report in the format desired by the client.

5.13.a.13(h)
The laboratory manager should be able to sign off on the data.

5.14(a)
Participants asked if written notification to the client is necessary; the Committee noted that initial notification might be by telephone but that it should be followed by written notification.

5.14(b)
The register of the subcontractor's accreditation should be maintained by the laboratory.

APPENDIX C

C.1
This section appears to be tailored toward specific U.S. Environmental Protection Agency (USEPA) measurements and should be generalized to include field measurements. Furthermore, the section is oriented toward measurements in water and should be revised to take into account the needs of other media. The initial demonstration of capability must be completed for a change of instrument type, as indicated in Section 5.10.2.1.

C.1(e)
Standard deviation and average recovery are not always the most appropriate ways to report results. Also, four samples are not always used. Acceptable variation in the analysis of multiple component mixtures should be addressed. The number of times the sample can be run to get everything within the acceptable range should also be addressed.

C.2
This section should stand on its own, separate from Section C.1. It was noted that Section C.2

should be rewritten to reflect analyses in the appropriate matrix and should indicate that these performance-based methods (PBMs) do not have definite requirements. New analytical methods must be validated, but each analyst does not need validation. The Committee added that broad matrix categories have been established and that these categories should be carefully defined by the Committee.

C.2.2.1
Different requirements for sampling in different media should be addressed; sampling is specified in Section 5.10.1.2.

C.2.2.1(12)
The word "last" should be "list."

C.2.2.1(28)
This paragraph is the same as paragraph 29. The discussion of limits of detection should be consistent with those of the other sections.

The participants suggested that a draft of the revised checklist be submitted to working laboratories to determine how well it will work before it is finalized.

C.2.3
This section is also included in the main section of Chapter 5.

APPENDIX D

D.1.1
Completing the component rotation within 2 years may be difficult. The measurement of the system would be better served by doing repetitive spikes with the same component; spiking mixtures could be chosen that are representative of all relevant chemistries. Multiple components must be used cautiously, however, as interference between components is possible.

D.4 -- Radioanalysis
The participants noted that positive and negative controls are not specified. The chair asked the participants to send comments to her on this section.

REVISIONS TO CURRENT STANDARDS

The participants noted that chapter 5 should be referred to as a "chapter" in the text rather than as "Section 5."

In Section 5.5.2(f), the person who can provide the approving signature should be clarified.

Section 5.6.2(c) could be furthered clarified by the use of bullets, and "of" should be added after "employees are aware."

In Section 5.9.3, the distinction between reference standard and calibration standard should be clarified.

It was noted that Section 5.9.4.2.1, as written, indicates that the temperature of laboratory refrigerators would have to be checked daily, even though no one might normally be in the building over the weekend. Furthermore, the seemingly excessive calibration called for might pose a burden for smaller laboratories. The Committee agreed that checking the refrigerator temperature on normal working days when in use would be sufficient.

Interpretation of the reagent record called for in Section 5.10.5(a) was requested, noting that recording the required information for reagent bottles would generate a lot of paperwork, frequently for very little purpose. The Committee noted that detailed records might be of use in tracking down the source of analytical errors but added that writing the date opened and the expiration date on the bottle would suffice.

Consideration of Section 5.11.5, calling for sample disposal SOPs, was deferred until a later meeting.

It was suggested that the acceptance limits specified in Section 5.9.4.3 regarding instrument calibration were too narrow; a 15% variation is too wide for some analyses and too narrow for others. Rather than meeting a specified range, the laboratories should be required to meet the requirements of the program being followed. A discussion followed about how a laboratory would demonstrate that wider limits are called for. The chair asked the participants to provide additional suggestions about how this might be demonstrated.

In Section 5.9.4.3 “r-squared” should be substituted for the correlation coefficient. The participants also inquired whether, with a 15% standard deviation, an “r-squared” of 0.995 is realistic.

Appendix B

The participants asked why a preparation batch is limited to 20 samples, adding that the preparation of method blanks may present a problem. The Committee noted that the 1:20 ratio is a balance between risk and economy, although some procedures may require a different ratio.

Appendix D

The participants noted that the reliance on method blanks is too rigid; if the blank is positive (i.e., contaminated) but the samples are negative, then whatever happened to the blank did not affect the samples and the data may be useable. The blanks should be considered in regard to the regulatory limits being analyzed for.

NEW CONCERNS

5.5.2(h)
The term "scope" was unclear. It was suggested to change "scope" to "the test methods the laboratory is qualified to employ".

5.11.5
The laboratory should have SOPs for proper waste disposal; the confidentiality of the client should be protected, although this is not required by NELAC.

5.12.4.5
Delete “receipt.” Safety problems are separate and outside the scope of NELAC.

5.12.3.1
NELAC certification should be limited to the analytical results and should not deal with safety, health, or other measures (see note in Section 5.7.1).

5.9.4.3
The word “demonstrated” will be considered later by the Committee.

5.4.2(f)
No educational requirements are specified for the quality assurance (QA) officer.

5.5.2.l
Facilities and services used by the laboratory should not include such services as plumbers and instrument repair technicians.

5.10.1.2
This section should reference SOPs where applicable.

D.1.4
This section is written too narrowly and does not address the needs of nonwater matrices such as analyses in air. Also, being able to reach the minimum detection limit (MDL) does not necessarily add to the ability of the laboratory to analyze its actual samples, which may be considerably more concentrated. In addition, this requirement would involve a great deal of time and might tie up an instrument for one month per year. The concept of MDLs is not even appropriate for some systems such as the real-time measurement of air samples. The requirement to analyze at this level should be reserved for those procedures actually analyzing at this level. Statistical issues regarding these samples should also be considered, such as how outliers in multiple samples should be handled. The chair asked the participants to provide her with further examples where MDLs are not appropriate.

Attachment A

ACTION ITEMS
Quality Systems Committee Meeting
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Item No.	ACTION	Date Completed
1	Ms. Labie asked that the participants provide her with: • Suggestions to make Section C.1 more general and applicable to other media.	
2	• Additional suggestions on the radioanalysis section.	
3	• Suggestions on the range of allowable detection limits given in Section 5.9.4.3.	
4	• Suggestions about the feasibility of requiring method detection limits (MDLs) to be stated for the analytical methods.	

Attachment B

LIST OF COMMITTEE PARTICIPANTS
Quality Systems Committee Meeting
February 4, 1997

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